EC Declaration of Conformity

EC Declaration of Conformity Annex II (excluding section 4) to Medical Devices Directive 93/42/EEC
Manufacturer: ALBYN MEDICAL S.L.
Manufacturer's Address: POLIGONO INDUSTRIAL CORDOVILLA calle D, nº 1, 31191 – CORDOVILLA – NAVARRA, SPAIN

Device/s: SMARTDYN
Description: Urine Urodynamic system
EC Product Class: IIa
CLASSIFICATION OF ME EQUIPMENT: CLASS II Medical equipment, externally powered, Type B applied part.

Albyn Medical S.L. declares that device SMARTDYN conforms to the relevant provisions of the EC Council Directive 93/42/EEC and the amendment 2007/47/EC and is in accordance with Annex II (excluding section 4), as implemented by the European Union's Medical Devices Regulations, as verified by our Notified Body, SGS United Kingdom Limited (Notified Body No. 0120)

Standards:

UNE EN ISO 14971:2012
Annex X MEDDEV 2.12/2
EN 1041:2008
IEC 62304:2006
EN 980:2008

Safety:
IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) third edition
EMC:
UNE-EN 60601-1-2:2008 + Corr:2010 (Medical Electrical Equipment)
Emission:
UNE-EN 55011:2011 + A1:11 (radiated emission)
Immunity:
UNE-EN 61000-4-2:10
UNE-EN 61000-4-3:07 + A1:08 + A2:11
UNE-EN 61000-4-4:05+A1:10
UNE-EN 61000-4-6:09
UNE-EN 61000-4-8:11

Albyn Medical S.L. confirms that no other application has been lodged with another Notified Body for the same device related Quality Management System.

Albyn Medical S.L. agrees to develop, implement and maintain a formally-recognized Quality Management System to ensure continued adequacy and efficacy.

Declaration of conformity				ALBYN MEDICAL Smart Medical Group			
Description	EC Declaration of Conformity SmartDyn			Document	SD14.1_4		
				Revision	4		
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Albyn Medical S.L. agrees to develop, implement and maintain a documented post-production experience monitoring process, including the notification of reportable events under the European Medical Device Vigilance System Guidelines.

Albyn Medical S.L. confirms that no medicinal products/drugs are incorporated in any devices covered by the Device Schedule.

Albyn Medical S.L. agrees to inform the appointed Notified Body of any planned or unplanned substantial change to the Quality Management System.

Albyn Medical S.L. agrees to inform the appointed Notified Body of any planned or unplanned significant change to the Device Schedule, including significant design change to devices.

Accessories included:

00004326 Puller for SmartDyn

00002785 Reusable pressure transducers

98800000/00004442 flowscale wireless/wired

00004617/00004618 EMG module

Signed by the Albyn Medical S.L. designated representative:

Gonzalo Buil
Quality Manager
16th of February 2016